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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/393,066	02/23/1995	JOHN H. WOLFE	PENN-0065	1030

7590 11/30/2006

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER
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Commissioner for Patents

The substitute Appeal Brief filed September 14, 2006, where the summary of claimed subject matter identifies specification support for the independent claims, has been entered.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit: 1632

Responsive to the Reply Brief on September 14, 2006, a supplemental Examiner's Answer is set forth below:

Appellant argues the examiner is in error in stating the present specification discloses the claimed invention as a therapy (Reply Brief, page 2, parag. 1). Appellant argues while the claims are drawn to methods of stably expressing a selected DNA sequence in the central nervous system of a mammal, the examiner's rejection appears to require precise predictability in treating CNS disorders (Reply Brief, page 2, parag. 3, lines 1-4). Appellant argues disclosing stable expression of a selected DNA sequence in the CNS of a mammal for at least 4 months and further disclosing the use of such stable expression as a method of treating CNS disorders satisfies the enablement requirement (Reply Brief, page 3, lines 6-11). These arguments are not persuasive.

Appellant has not provided any specification support for a use of the claimed method absent gene therapy. Therefore, the claimed method must meet the requirements of 35 U.S.C. § 112 for enablement. There has been no requirement for precise predictability, just predictability without undue experimentation. The rejection has been made with support from Fink et al, Blomer et al, Eck et al, and Wolfe et al. Appellant has not provided any evidence that at least 4 months of expression overcomes the expression concerns of these references.

Appellant argues the how to use prong of section 112 incorporates as a matter of law the requirement under 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility (Reply Brief, page 3, parag. 2, lines 1-4). Appellant argues the rejection appears to question whether gene therapy is a credible utility (Reply Brief, page 3, parag. 2, lines 6-8). These arguments are not persuasive.

While 35 U.S.C. § 112, first paragraph requires an enabled use, this is a separate rejection from a lack of utility rejection made under 35 U.S.C. § 101. The two are not the

same rejection. A claim can lack enablement but have utility according to present PTO examination guidelines. As a rejection under 35 U.S.C. § 101 is not of record, there is no reason to argue such. In particular, there is no rejection of record that states the claims lack credible utility. The issue is whether or not the showing of 4 month stable expression is sufficient to enable a treatment in view of teachings in the art. The claims lack an enabled use as set forth in the Examiner's Answer mailed August 18, 2006.

Appellant argues neurotrophic viral vectors at the time of filing were recognized as useful for the purpose of gene delivery in the treatment of diseases, and cites Fink et al (1996) and Eck et al (1996) (Reply Brief, page 4, lines 6-10). Appellant argues by stating the claimed method can be used in a method of therapy is sufficient for enablement (Reply Brief. page 4, lines 10-15). Appellant argues that a claimed invention must be capable of performing some beneficial function and expression for at least 4 months is such a beneficial function (Reply Brief, page 4, lines 21-25). These arguments are not persuasive.

Fink et al and Eck et al outline the myriad problems associated with neurotrophic viral vectors, such as HSV, and set forth several factors which they state question the use of these vectors in gene therapy (Examiner's Answer, mailed August 16, 2006, pages 5-6). There is no evidence of record that stable expression for at least 4 months is sufficient to overcome the lack of therapeutic effect outline by Fink et al and Eck et al. While expression for at least 4 months maybe beneficial, there is no evidence the benefit is in gene therapy uses.

Appellant may file another reply brief in compliance with 37 CFR 41.41 within two months of the date of mailing of this supplemental examiner's answer. Extensions of time under 37 CFR 1.136(a) are not applicable to this two month time period. See 37 CFR 41.43(b)-(c).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

November 27, 2006

A Technology Center Director or designee has approved this supplemental examiner's answer by signing below:

JOHN LEGUYADER
DIRECTOR
TECHNOLOGY CENTER 1600